

OSE Immunotherapeutics Publishes Positive Preclinical COVID-19 Vaccine Results With Multi-Target Vaccine CoVepiT

- Data support potential as novel and differentiated COVID-19 vaccine designed against multiple SARS-CoV-2 targets with technology known to induce memory T lymphocytes
- Studies show that CoVepiT provides tissue-resident memory (Trm) sentinel T cell response with long-term protective immunity in barrier tissues such as the respiratory tract and the lung
- Clinical entry expected by end of 2020/early 2021

Nantes, France, August 17th, 2020, 7:30AM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnémo: OSE) today announced the online **publication** in BioRxiv of positive data from preclinical and human *ex vivo* studies with CoVepiT, its prophylactic vaccine program based on optimized peptides selected to induce a lasting sentinel T lymphocyte immune response against SARS-CoV-2, the virus that causes COVID-19, in barrier tissues such as the respiratory tract and the lung.

Nicolas Poirier, Chief Scientific Officer of OSE Immunotherapeutics, commented: *“The CoVepiT program is based on a clinically-validated technology now shown to induce tissue-resident memory T lymphocytes (Trm) sentinel response against multiple parts of SARS-CoV-2, suggesting it provides a long-term protective immunity, as opposed to transient protection provided by neutralizing antibodies^(1, 2, 3, 4). In addition, this vaccine is designed to anticipate ongoing recurrent virus mutation and evolution, further adding to its long-term protective potential. T-cell epitopes were also selected based on the natural immunity observed against our peptides in convalescent COVID-19 patients. Generated using our Memopi[®] vaccinal technology, which has already shown good tolerance and efficacy in a large number of cancer patients, these data build a strong basis to pursue the development of this 2nd generation of SARS-CoV-2 vaccine focused on memory CD8 T cell technology.”*

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, concluded: *“We are rapidly advancing our fight against COVID-19, a major public health issue, with a vaccine program especially designed for people at risk, including older adults and immunocompromised populations. Initial preclinical results were strengthened by a parallel human *ex-vivo* study conducted in two clinical centers. We warmly thank Dr. Didier Debieuvre, of the Hospital Center Emile Müller of Mulhouse and Dr. Matthieu Le Flem of the Marine Firefighters of Marseille for their involvement and support in this study. Based on the positive data published today, we look forward to evaluating CoVepiT's efficacy in a Phase 1 clinical study expected to be initiated by the end of 2020/early 2021.”*

The article, entitled: “*Tissue-resident memory CD8 T-cell responses elicited by single injection of a multi-target COVID-19 vaccine,*” was published on **BioRxiv**, an open access preprint repository. It reports that:

- CoVepiT showed strong induction of memory CD8 T lymphocytes against multiple SARS-CoV-2 proteins in vaccinated humanized mice. This validates the novel approach based on selected and optimized peptides (neoepitopes) improved using artificial intelligence algorithms to increase immunogenicity and better induction of memory T cells.
- Humanized mouse model studies demonstrated a promising phenotype of Tissue-resident memory T cells (Trm) elicited after vaccination. These cells act as sentinels in barrier tissues and are well known to eliminate infected cells before significant virus replication.
- Convalescent (asymptomatic, moderate, and severe) COVID-19 patients displayed strong memory T cells responses against our multi-target peptides, validating the potential for these peptides to naturally induce memory T cells responses.
- Selection and generation of SARS-CoV-2 multi-target peptide vaccine (targeting Spike, M, N, and several non-structural proteins), covered for heterogeneity and already recurrent mutation, observed in up to 46,000 SARS-CoV-2 sequences isolated worldwide and for future virus evolution.
- Further selection of peptides with high homology to previous endemic coronaviruses (particularly SARS-CoV-1 of 2002) anticipates future emergence of new coronaviruses.

The CoVepiT preclinical phase program was supported by funding from Nantes Metropole as part of the *Metropolitan Fund to Support Health Innovations Linked to the COVID-19 Health Crisis*, a fund created by Nantes Metropole for health innovations to address the COVID-19 health crisis.

To access to the online publication in BioRxiv, click [here](#)

- (1) Wu et al. Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered 2 patient cohort and their implications MedRxiv April 6, 2020
- (2) Huang et al. A systematic review of antibody mediated immunity to coronaviruses: antibody kinetics, correlates of protection, and association of antibody responses with severity of disease. MedRxiv April 17, 2020
- (3) Tang et al. Lack Peripheral Memory B Cell Responses in Recovered Patients with Severe Acute Respiratory Syndrome: A Six-Year Follow-Up Study. Journal of Immunology 2011
- (4) Ho et al. Neutralizing Antibody Response and SARS Severity. Emerg Infect Dis. 2005

ABOUT CoVepiT:

The CoVepiT vaccine is a neoepitope vaccine intended to prophylactically protect against infections with SARS-CoV-2, the virus that causes COVID-19. The vaccine incorporates optimized peptide fragments (neoepitopes) improved using artificial intelligence algorithms to increase immune response and induce strong memory T cell responses. Selection and generation of SARS-CoV-2 targets (including Spike, M, N, and several non-structural proteins) was based on homology seen in 46,000 SARS-CoV-2 samples isolated worldwide, helping ensure vaccine effectiveness even with future evolution of the virus. CoVepiT is generated using OSE's proprietary Memopi® technology which has been validated for both safety and efficacy through the step-1 of Phase 3 clinical phase of neoepitope vaccine Tedopi® in patients with non-small lung cancer.

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company has several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical and preclinical portfolio has a diversified risk profile:

- **Tedopi®** (innovative combination of neoepitopes) : the company's most advanced product; **positive results for Step-1 of the Phase 3 trial** (Atalante 1) in **Non-Small Cell Lung Cancer** post checkpoint inhibitor failure; due to Covid-19, voluntary definitive stop of new patient accrual in the Step-2 initially planned in the trial. In **Phase 2 in pancreatic cancer** (TEDOPaM, sponsor GERCOR) in combination with checkpoint inhibitor Opdivo®.
- **BI 765063** (OSE-172, anti-SIRPα monoclonal antibody): developed in **partnership with Boehringer Ingelheim**; myeloid checkpoint inhibitor in **Phase 1 in advanced solid tumors**.
- **FR104** (anti-CD28 monoclonal antibody): **positive Phase 1 results; Phase 2-ready asset in autoimmune diseases or in transplantation**.
- **OSE-127** (humanized monoclonal antibody targeting IL-7 receptor): developed in **partnership with Servier**; **positive Phase 1 results**; two independent **Phase 2** planned in **ulcerative colitis** (OSE sponsor) and in **Sjögren's syndrome** (Servier sponsor) to start in 2020.
- **BiCKI®**: **bispecific fusion protein** platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2nd generation of PD-(L)1 inhibitors to increase **antitumor efficacy**. **Additional innovative research programs**.
- **CoVepiT**: a **prophylactic vaccine** against **COVID-19**, developed using SARS-CoV-2 optimized neo-epitopes. **Positive preclinical and human ex vivo results in August 2020, clinical trial expected to start end of 2020/early 2021**.

Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127 could be impacted during the coming months.

For more information: <https://ose-immuno.com/en/>

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Contacts

OSE Immunotherapeutics

Sylvie Détry
Sylvie.detry@ose-immuno.com
+33 153 198 757

French Media: FP2COM

Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

U.S. Media: LifeSci Communications

Darren Opland, Ph.D.
darren@lifescicomms.com
+1 646 627 8387

U.S. and European Investors

Chris Maggos
chris@lifesciadvisors.com
+41 79 367 6254

Forward-looking statements

This press release contains express or implied information and statements that might be deemed forward-looking information and statements in respect of OSE Immunotherapeutics. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE Immunotherapeutics' management in light of its experience and its perception of historical trends, current economic and industry conditions, expected future developments and other factors they believe to be appropriate.

These forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import. Although the OSE Immunotherapeutics management believes that the forward-looking statements and information are reasonable, the OSE Immunotherapeutics' shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE Immunotherapeutics. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or



identified in the public filings made by OSE Immunotherapeutics with the AMF. Such forward-looking statements are not guarantees of future performance. This press release includes only summary information and should be read with the OSE Immunotherapeutics Universal Registration Document filed with the AMF on 15 April 2020, including the annual financial report for the fiscal year 2019, available on the OSE Immunotherapeutics' website. Other than as required by applicable law, OSE Immunotherapeutics issues this press release at the date hereof and does not undertake any obligation to update or revise the forward-looking information or statements.